

### **REMARKS**

In this Amendment, claims 21, 22, and 38 have been amended. No new matter has been added. Claims 21-38, 40-46, 48-54, 56, 57 and 63 are currently pending in this application.

#### **Obviousness rejections over Muller are Overcome**

Claims 21-38, 40-46, 56 and 57 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Muller et al. in view of U.S. Patent No. 5,739,152 to Andersson et al. There are no claim rejections applied to claims 48-54. Applicants request clarification whether claims 48-54 are rejected or whether these claims contain allowable subject matter.

Applicants' claims 21-38, 40-46, 56 and 57 differ from Muller in that they recite specific ratios of biologically active substances to phospholipids and also include a specific type of surfactant, whereas these ratios and surfactants are not taught in Muller. The Examiner's position is that even though Muller discloses none of the critical limitations of the claimed invention, the "determination of optimum proportions or amounts of active ingredients are considered to be within the skill of the artisan." The Examiner further states that the use of the word "containing" permits the addition of other agents.

Without acceding to the propriety of the Examiner's position, and in order to facilitate prosecution, applicants have amended independent claims 21, 22, and 38 to recite "consisting essentially of" instead of "containing". The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). *MPEP* 2111.03. The specified materials of the instant claims include a water insoluble active substance with a specified mean particle size, a phospholipid surface modifier present in a specified amount, a specified ratio of active substance to phospholipid surface modifier, and specifically exclude the use of any surfactants that require cloud point modifying molecules for protection against coagulation during the autoclave process. Muller does not teach any of these specified claim elements. Applicants submit that the claims as amended are thus patentable over the disclosure of Muller.

The Andersson disclosure does not cure the deficiencies in Muller. Accordingly, the combination of Andersson with Muller also does not render obvious the presently amended claims. Applicants submit that the claims as amended overcome the obviousness rejections and are now allowable.

### CONCLUSION

Applicants respectfully submit that the present application is now in condition for allowance. Should any additional fees be required, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. **50-0311**; Reference No. **28069-503**.

Respectfully submitted,

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